

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

OREXO AB,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC. and
MYLAN INC.,

Defendants.

Civil Action No. 3:11-cv-3788-MAS-LHG

Hon. Michael A. Shipp, U.S.D.J.
Hon. Lois H. Goodman, U.S.M.J.

Motion Return Date: August 6, 2012

Document Filed Electronically

**REPLY BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.
AND MYLAN INC.'S MOTION TO SEAL PORTIONS OF THE JOINT CLAIM
CONSTRUCTION AND PREHEARING STATEMENT AND EXHIBITS THERETO**

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“Orexo does not dispute that portions of Mylan’s ANDA are confidential.” (Orexo’s Opp’n Br. at 3.) Orexo recognizes Mylan’s ability to seal “confidential or proprietary information from public view.” (Orexo Opp’n Br. at 2.) Nevertheless, in an opposition that lacks specifics, Orexo opposes Mylan’s motion to seal those portions of the joint claim construction statement that reveal Mylan’s confidential formulation of Mylan’s zolpidem product—as disclosed in Mylan’s confidential ANDA. Orexo apparently opposes Mylan’s motion because Orexo simply does not agree that Mylan’s proposed claim constructions reveal Mylan’s confidential formulation and Orexo contends that Mylan is seeking to seal public information. The Court should reject Orexo’s argument because, as set forth below, Orexo is wrong on both counts and relies on incorrect factual predicates.

I. THE CLAIM CONSTRUCTIONS IN DISPUTE REVEAL PORTIONS OF MYLAN’S CONFIDENTIAL FORMULATION

Orexo argues that Mylan’s motion should be denied because claim constructions are not to be based on the product at issue and are based on “publicly available evidence.” It further argues that Mylan failed to “connect the dots” by identifying the confidential information included in the joint claim construction statement. (Orexo Opp’n Br. at 3.)

Evidently, Orexo would prefer that Mylan reveal its highly confidential information in its motion to seal papers, even though such motions are publicly available under L. Civ. R. 5.3(c)(2). To follow Orexo’s approach would eviscerate Mylan’s claim of confidentiality with respect to its formulation—the very information that Mylan is trying to protect. Without prejudice to Mylan, we respectfully submit that a general discussion of the issue demonstrates that the proposed claim constructions reveal Mylan’s confidential information.

With respect to the “bioadhesion and/or mucoadhesion promoting agent” portion of the “ordered mixture...” limitation, Orexo has taken the position that Mylan’s use of a certain

ingredient satisfies the claim's requirement for a "bioadhesion and/or mucoadhesion promoting agent." As shown in a redacted excerpt of Mylan's proposed claim construction below, Mylan proposes that the term "bioadhesion and/or mucoadhesion promoting agent," as properly construed in Orexo's patent and based on the intrinsic evidence, explicitly excludes that ingredient:

Bioadhesion and/or mucoadhesion promoting agent

A substance that is effective in making the active agent adhere to the oral mucosa.

For the '910 patent, neither [Ingredient A] nor [Ingredient B] is such an agent.

(Joint Claim Construction and Prehearing Statement (ECF No. 63) at p. 26, Att. 3, Col. 2.)

Both parties agree that this term (as well as the other construction that Mylan seeks to seal) are "central to Mylan's primary non-infringement allegations." (*See* Joint Claim Construction and Prehearing Statement (ECF No. 63) at 13-14.) It is no wonder, then, that the proposed constructions of these terms reveal aspects of Mylan's confidential formulation for Mylan's zolpidem tartrate sublingual tablets. The parties, of course, would ask the Court to construe only claim terms that are relevant to the issues in the case. *See, e.g., O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[C]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." (quoting *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997))).) Mylan crafted its proposed construction, which is based on the intrinsic evidence of Orexo's patent, to highlight a key infringement dispute before the Court. As such, one need not be a formulation scientist to make the appropriate inference that Mylan's product incorporates one or both of

Ingredients A and B. Mylan's proposed construction relevant to this dispute undeniably reveals that portion of Mylan's highly confidential formulation.

Mylan's generic competitors could use that information to develop competing zolpidem tartrate products that—like Mylan's product—are bioequivalent to Orexo's product but do not infringe Orexo's patent. Accordingly, in order to protect Mylan's highly confidential and proprietary information, Mylan's claim constructions should not be disclosed or otherwise available on the public docket.

II. MYLAN HAS NOT WAIVED THE CONFIDENTIALITY OF THE DESIGNATED INFORMATION

Orexo argues that Mylan's motion should be denied because Mylan failed to designate this information as highly confidential in the parties' exchanges of information during the meet-and-confer process. (*See, e.g.*, Orexo Opp'n Br. at 2.) Mylan, however, has now corrected its inadvertent failure to designate the constructions as Confidential and served versions of those disclosures with the appropriate confidentiality designation on July 30, 2012 pursuant to the Discovery Confidentiality Order. Under paragraph 10(b) of the Court's Discovery Confidentiality Order, a party does not waive the right to designate information as confidential if it inadvertently failed to designate the information as confidential.

Orexo next contends that it already has discussed Mylan's confidential information with "Orexo," but its papers notably do not claim that this included anyone at Orexo who is not permitted access to Mylan confidential information under the Discovery Confidentiality Order.¹ (Orexo Opp'n Br. at 2.) In any event, the fact that *Mylan* may have been injured by disclosure to

¹ A number of Orexo personnel are permitted access to the ANDA and other confidential information under the Discovery Confidentiality Order; these are the people who, according to Orexo, are able to analyze Mylan's product in light of Orexo's patent. (See Discovery Confidentiality Order (ECF No. 47) at ¶ 4(b)(1)(b).)

unidentified people at Orexo is not support for compounding that injury by publicly disclosing this information about Mylan's formulation to Mylan's competitors.

Orexo next suggests that its ability to litigate the case will be hampered if Mylan's confidential information is filed under seal (Orexo Opp'n Br. at 3-4), but that is always the case when a litigation involves confidential information. The Discovery Confidentiality Order contemplates that counsel will not be able to share all relevant information with their clients. (Discovery Confidentiality Order (ECF No. 47) at ¶ 4.) This is not a reason to deny Mylan's motion to seal portions of the record.

III. MYLAN HAS NOT SOUGHT TO SEAL PUBLIC INFORMATION

Similarly, Orexo incorrectly contends—without citation or specifics—that Mylan is seeking to seal citations to publicly available evidence. (Orexo Opp'n Br. at 3.) Orexo's failure to cite any alleged publicly available evidence that Mylan is seeking to seal is telling—because Mylan is not seeking to seal *any* publicly available evidence. Mylan invites the Court to review Exhibit C to the Koutsoubas Declaration, which provides a line-by-line description of the nature of each piece of information that Mylan seeks to seal. As shown in Exhibit C, Mylan is seeking to seal only 1) Mylan's own proposed constructions;² 2) Mylan's or Orexo's characterizations of Mylan's constructions; or 3) Mylan's additional commentary related to its own citation of evidence that reveals Mylan's proposed constructions. Contrary to Orexo's statements, and even

² Mylan notes that its motion also seeks to seal Orexo's proposed constructions of the same terms. Orexo's proposed constructions reveal Mylan's confidential information when viewed together with Mylan's proposed constructions. If Mylan's proposed constructions—and any discussion related to Mylan's proposed constructions—are sealed, the public filing of Orexo's constructions no longer provides sufficient information to disclose Mylan's confidential information. Accordingly, Mylan withdraws its request to seal Orexo's proposed constructions and submits a revised proposed order and redacted version of the Joint Claim Construction and Prehearing Statement to that effect, attached hereto as Exhibits A and B to the Koutsoubas Declaration, respectively.

taking into consideration Orexo's constructions, Mylan has not sought to seal citations to publicly available information.

CONCLUSION

Orexo's agreement that it is proper to seal information from Mylan's ANDA and Mylan's formulation should end the inquiry. Orexo bases its opposition to Mylan's motion on mischaracterizations of the limited information that Mylan seeks to seal. Mylan respectfully requests that the Court seal the portions of the Joint Claim Construction and Prehearing Statement (and exhibits) identified in its revised proposed order.

Dated: July 30, 2012

Respectfully submitted,

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